

In the Specification:

- On page two, please amend the first, second, and third full paragraphs to read as follows:

In one aspect, the invention relates to a suturing instrument. The suturing instrument includes an elongate body member, a needle deployment system disposed at a distal portion of the elongate body member. The needle deployment system includes a forward-deploying needle carrier including a needle for tissue penetration and a catch to receive and retain the needle. The inclusion of a needle catch in the needle deployment system prevents the need for the introduction of a second surgical instrument into the location of the body where the suture was passed in order to retrieve the suture.

A2 In some embodiments, the suturing instrument may include a deployment controller having a proximal end and a distal end. The deployment controller extends substantially along a longitudinal axis of the elongate body member to the distal portion of the elongate body member, where the distal end of the deployment controller is coupled to the needle carrier and moves the needle carrier between a retracted position and a deployed position. The proximal end of the deployment controller may be coupled to an actuator. In some embodiments, the deployment controller guides the needle carrier along a path which includes a proximal curved path segment such that the needle carrier initially travels away from the elongate body member and then toward the elongate body member.

Various embodiments according to the foregoing aspect of the invention can include the following features. A suture can include a needle, and the needle can be permanently fixed to an end of the suture. The needle fixed on the suture can insert into the needle carrier. Also, the needle can be plastic, metal, or polymer compound. In addition, the suturing instrument can include a catch to receive and retain the needle, where the catch is positioned on the elongate body member such that a distal segment of the needle carrier's path is intercepted by the catch. Additionally, the suturing instrument may include a second needle carrier and a second forward-directed exit port. Further, the deployment controller may be coupled to the needle carrier with a flexible driver member. The flexible driver member may be manufactured of an alloy that includes at least or exclusively nickel and titanium.

- [• On page two, please amend the last paragraph to read as follows:]

In yet another embodiment, the invention relates to a suturing instrument including an elongate body member having a longitudinal axis and a distal tip needle deployment assembly joined with a distal end of the elongate body member such that the distal tip assembly is free to rotate axially about the longitudinal axis of the elongate body member. The distal tip needle deployment assembly includes a forward-directed needle exit port and a curved needle carrier channel formed in the distal tip needle deployment assembly, a curved needle carrier movably positioned in the curved needle carrier channel, a suture with an attached needle tip, and a deployment controller including a proximal end and a distal end. The deployment controller extends substantially along the longitudinal axis of the elongate body member to the distal end of the elongate body member, where the distal end of the deployment controller is coupled to the distal tip suture deployment assembly and moves the curved suture carrier through the curved suture carrier channel as the deployment controller moves between a retracted position and a deployed position. Additionally, the proximal end of the deployment controller may be coupled to an actuator.

- Q2 [• On page three, please amend the first full paragraph to read as follows:]

In still another embodiment, the invention relates to a suturing instrument including a body member defining a forward-directed exit port and a needle carrier channel, a needle carrier movably positioned in the needle carrier channel, and a surgical needle attached with an interference fit on a distal end of the needle carrier. The needle carrier has a retracted position within an interior region of the body member and a deployed position exterior to the body member. The needle carrier is configured within the needle carrier channel such that the needle carrier exits the interior region of the body member through the forward-directed exit port. In addition, the forward-directed exit port, needle carrier channel, and needle carrier can be located in a distal tip assembly coupled to the body member, and the distal tip assembly can be coupled to the body member such that the distal tip assembly is free to rotate axially about a longitudinal axis of the body member. In addition, the needle carrier and needle catch can be located in a distal tip assembly coupled to the elongate body member at a pivot joint such that the distal tip assembly is free to deflect about the pivot joint. Such embodiments described above allow for enhanced control of the precise placement or position of the distal tip of the suturing instrument.

- Q2 • On page three, please amend the last paragraph to read as follows:]

An additional aspect of the invention relates to a method for placing a suture in tissue. The method includes the steps of placing a suturing instrument enclosing a needle carrier having an attached needle for tissue penetration, deploying the needle carrier out of the suturing instrument through a forward-directed exit port such that the needle carrier exits an interior region of the suturing instrument through the exit port along a path which approaches being substantially tangential to an outer surface of the suturing instrument surrounding the forward-directed exit port, and capturing a needle attached to a suture and carried by the needle carrier in a catch that receives and retains the needle. The needle carrier is movably positioned within a needle carrier channel adjacent the tissue to be sutured.

- Q3 • On page six, please amend the fourth, fifth, and sixth full paragraphs to read as follows:

FIGS. 5A and 5B are perspective views of an alternate catch mechanism with a needle carrier.

FIG. 6 is an end view illustrating the formed needle tip catch.

FIG. 7 is a cross-sectional view of the needle tip catch shown in FIG. 6.

- Q4 • On page six, please amend the eleventh full paragraph to read as follows:

FIG. 1 illustrates the general structure of one embodiment of the present invention. FIG. 1 depicts a suturing instrument 100 including handle 105, an elongate body 110, a distal tip 115, and an actuator button 120. This embodiment of the present invention is particularly well suited to, for example, the fixation of sutures to the pelvic floor during a procedure to effectively shorten the pelvic floor for the treatment of hypermobility. As will become apparent, this embodiment includes features that prevent the need for positioning the target tissue between the needle exit port and the needle catch on the side of a distal tip while placing the suturing instrument in the body. The embodiment of FIG. 1 allows for the positioning of the target tissue between the needle exit port and the needle catch on the front face of the distal tip 115 during the placement of the suturing device into the body. The end of the distal tip 115 may be pressed against the target tissue in order to throw a suture into the tissue.

- On page seven, please amend the second full paragraph to read as follows:

AS
The needle carrier 255 shown in FIG. 2 is circular; however, it is contemplated that the above embodiment may be modified to include needle carriers having non-circular contours (e.g., helical, elliptical, or straight). Although a single needle carrier 255 is shown in the figure, the above configuration may in fact contain more than one needle carrier. For example, multiple needle carriers may be actuated and driven independently by dividing the deployment controls and the needle carrier drivers into separate adjacent members with separate handles or controlled by a single handle.

- On page seven, please amend the fourth full paragraph to read as follows:

AL
A needle tip 305 comprises a body 310 having a shoulder 315. The shoulder 315 is the rear surface of the needle tip body 310 that engages a catch 260 in the manner of a flange. A length of suture material 300 is inserted into a hole 320 located on the body 310 and attached to the needle tip 305 thereby. The suturing material 300 is attached to the body 310 by any suitable means, such as crimping or adhesive bonding. It should be understood that the illustrated arrow-shaped body 310 is merely illustrative, and the shape may be varied to fit a particular application. The needle tip 305 can be manufactured from a plastic, metal, or polymer compound and can be formed by, for example, extrusion, molding, or machining. Furthermore, the nature of the suture 300 is immaterial to the present invention. The needle tip 305 of the present invention may be used with a suture of any type, length, diameter, and characteristics.

- On page nine, please amend the last paragraph to read as follows:

AL
Moreover, distal tip 815 may be rotatable about the axis of the elongate body housing 810 as shown in FIGS. 8B-8D. For example, an actuator button 820 may be secured to the distal tip 815 through housing 810. Rotation of the actuator button 820 causes a corresponding rotation of the distal tip 815. The actuator button 820 may include a directional indicator 855 such as a pointed shape on the actuator button 820 that is aligned with the plane in which the needle tip (not shown) travels during deployment of the device 800. FIGS. 8C and D depict the rotation of the distal tip 815 by 90 degrees in alternative directions from the starting position depicted in FIG. 8B. Additionally, the range of rotation of the distal tip 815 may include a complete 360 degrees about the axis of the elongate body housing 810.

- On page eleven, please amend the first full paragraph to read as follows:

Q8

FIGS. 10A-F depict a surgical method for treating hypermobility in women involving the passing of two sutures into the pelvic floor. The surgical method includes placing the distal tip 1000 of a surgical device 1005 (partially shown) against the surface of the pelvic floor 1010 and deploying the device so that the needle carrier 1015, which is carrying a needle tip 1020 with an attached suture 1025, moves in the direction of the arrow and pierces the pelvic floor 1010 (FIG. 10A). The needle carrier 1015 carries a needle tip 1020 into the needle catch 1030 in the distal tip 1000. In FIG. 10B the needle carrier 1015 is retracted into the distal tip 1000, and while the needle tip is retained in the needle catch 1030 the distal tip 1000 is retracted from the surface of the pelvic floor 1010. The needle tip 1020 is extracted from the needle catch 1030 (FIG. 10B) and reloaded into the needle carrier 1015 (FIG. 10C). In FIG. 10D the suture 1025 is placed in the pelvic floor 1010 in a second location a certain distance from the first suture placement. In FIG. 10E the needle carrier 1015 is retracted into the distal tip 1000, and the needle tip is retained in the needle catch 1030. The retention of the needle tip 1020 in the needle catch 1030 allows for the retention and control of the leading end of the suture 1025 while the distal tip 1000 is retracted from the surface of the pelvic floor 1010 (FIG. 10E). In FIG. 10F the suture 1025 remaining in the pelvic floor 1010 is tightened and tied thus causing the buckling and effective shortening of the pelvic floor 1010. The distance between the two suture placements is directly proportional to the degree to which the pelvic floor 1010 can be shortened. The degree to which the pelvic floor 1010 is shortened can also be controlled by how tightly the suture 1025 is drawn in and tied.

In the Claims:

Please amend claims 1, 7-9, 11-13, and 20 to read as follows:

- Q9
1. (Amended) A suturing instrument comprising:
an elongate body member; and
a needle deployment system disposed at a distal portion of the elongate body member, the needle deployment system comprising
a forward-deploying needle carrier,
a needle catch to receive and retain a needle, and
a forward-directed exit port, wherein the needle catch and the exit port are
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